



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS-10260, CMS-R-297/CMS-L564, CMS-4040, CMS-10718 and CMS-10146]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by **[INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>
2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10260 Medicare Advantage and Prescription Drug Program: Final Marketing Provisions in 42 CFR 422.111(a)(3) and 423.128(a)(3)

CMS-R-297/CMS-L564 Request for Employment Information

CMS- 4040 Request for Enrollment in Supplementary Medical Insurance (SMI) and Supporting Regulations in 42 CFR 407.10, 407.11 and 408.40(a)(2)

CMS-10718 Model Medicare Advantage and Medicare Prescription Drug Plan Individual Enrollment Request Form

CMS-10146 Notice of Denial of Medicare Prescription Drug Coverage

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Medicare Advantage and Prescription Drug Program: Final Marketing Provisions in 42 CFR 422.111(a)(3) and 423.128(a)(3); *Use:* Pursuant to disclosure requirements set out in sections 1851(d)(2)(A) and 1860D-1(c) of the Social Security Act (the Act), and cited in §§422.111(a)(3) and 423.128(a)(3), Medicare Advantage (MA) organizations

and Part D sponsors must provide notice to plan members of impending changes to plan benefits, premiums and cost sharing in the coming year. To this effect, members will be in the best position to make an informed choice on continued enrollment or disenrollment from that plan at least 15 days before the Annual Election Period (AEP) using the Annual Notice of Change (ANOC) and before the first day of the AEP for the Evidence of Coverage (EOC). MA organizations and Part D sponsors must notify plan members of the coming year changes using the standardized ANOC. Plans must disseminate the EOC at the time of enrollment and at least annually thereafter.

CMS requires MA organizations and Part D sponsors to use the standardized documents being submitted for OMB approval to satisfy disclosure requirements mandated by section 1851 (d)(3)(A) of the Act and §422.111 for MA organizations and section 1860D-1(c) of the Act and §423.128(a)(3) for Part D sponsors.

Sections 1851(h)(1) and (2) of the Act require MA organizations and Part D sponsors to obtain CMS approval of marketing materials to ensure that MA organizations and Part D sponsors disclose correct information to current and potential enrollees. CMS collects and retains the MA organization and Part D plan marketing materials via the Health Plan Management System (HPMS). MA organizations and Part D plans submit marketing materials to the CMS marketing material review process using HPMS. Both current and potential enrollees can review other marketing materials to find plan benefits, premiums, and cost sharing for the coming year (after October 1) and the current year to be in a better position to make.

MA organizations and Part D sponsors use the information discussed in the Medicare Communication and Marketing Guidelines (MCMG) to comply with the requirements to seek CMS approval on marketing materials under MA and Part D law and regulations, as described above. CMS requires MA organizations and Part D sponsors to obtain CMS approval of marketing

materials to ensure that MA organizations and Part D sponsors disclose correct information to current and potential enrollees. Both current and potential enrollees can review other marketing materials to find plan benefits, premiums, and cost sharing for the coming year (after October 1) and the current year to be in a better position to make informed and educated plan selections. *Form Number:* CMS-10260 (OMB control number: 0938-1051); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 795; *Total Annual Responses:* 47,962; *Total Annual Hours:* 33,124. (For policy questions regarding this collection contact Timothy Roe at (410) 786-2006.)

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Request for Employment Information; *Use:* The form CMS-L564, also referred to as CMS-R-297, is used, in conjunction with form CMS-40-B, Application for Supplementary Medical Insurance, during an individual's special enrollment period (SEP). Completed by an employer, the CMS-L564 provides proof of an applicant's employer group health coverage. The Social Security Administration (SSA) uses it to obtain information from employers regarding whether a Medicare beneficiary's coverage under a group health plan is based on current employment status. This form is available in both English and Spanish.

Section 1837(i) of the Social Security Act (the Act) provides a SEP for individuals who delay enrolling in Medicare Part B because they are covered by a group health plan based on their own or a spouse's current employment status. Disabled individuals with Medicare may also delay enrollment because they have large group health plan coverage based on their own or a family member's current employment status. When these individuals apply for Medicare Part B, they must provide proof that the group health plan coverage is (or was) based on current employment status. Form CMS L564 provides this proof so that SSA can determine eligibility for the SEP. Individuals

eligible for the SEP can enroll in Part B without incurring a late enrollment penalty. Individuals may also use this form to prove that their group health plan coverage is based on current employment status and to have the assessed Medicare late enrollment penalty reduced.

The form is available online via Medicare.gov and CMS.gov for individuals who are requesting the SEP to obtain and submit to their employer for completion. The employer must complete and sign the form, and submit it to the individual to accompany their enrollment or late enrollment penalty reduction request. The information on the completed form is reviewed manually by SSA. Thus, the collection of this information does not involve the use of information technology. *Form Number:* CMS-R-297/CMS-L564 (OMB control number: 0938-0787); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 15,000; *Total Annual Responses:* 15,000; *Total Annual Hours:* 1,250. (For policy questions regarding this collection contact Carla D. Patterson, at (410) 786-1000.)

3. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Request for Enrollment in Supplementary Medical Insurance (SMI) and Supporting Regulations in 42 CFR 407.10, 407.11 and 408.40(a)(2); *Use:* Section 1836 of the Social Security Act, and CMS regulations at 42 CFR 407.10, provide the eligibility requirements for enrollment in Part B for individuals age 65 and older who are not entitled to premium-free Part A. The individual must be a resident of the United States, and either a U.S. Citizen or an alien lawfully admitted for permanent residence that has lived in the US continually for 5 years.

CMS regulations 42 CFR 407.11 lists the CMS-4040 as the application to be used by individuals who are not eligible for monthly Social Security/Railroad Retirement Board benefits or free Part A.

The CMS-4040 solicits the information that is used to determine entitlement for individuals who

meet the requirements in section 1836 as well as the entitlement of the applicant or their spouses to an annuity paid by OPM for premium deduction purposes. The application follows the application questions and requirements used by SSA. This is done not only for consistency purposes but to comply with other Title II and Title XVIII requirements because eligibility to Title II benefits and free Part A under Title XVIII must be ruled out in order to qualify for enrollment in Part B only.

Form Number: CMS- 4040 (OMB control number: 0938-0245); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 29,663; *Total Annual Responses:* 29,663; *Total Annual Hours:* 7,416 hours. (For policy questions regarding this collection contact Carla D. Patterson, at (410) 786-1000.)

4. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Model Medicare Advantage and Medicare Prescription Drug Plan Individual Enrollment Request Form; *Use:* This information collection is necessary for the Medicare beneficiary (or their legal representative), to enroll in an MA or PDP plan, even if switching plans within the same MA or PDP organization. To consider an election complete, the individual must:

- Complete an enrollment request;
- Provide required information to the MA or PDP organization within the required time frames;
- Submit the completed request to the MA or PDP organization during a valid enrollment period.

MA and PDP organizations, applicants to MA and PDP organizations, and the CMS will use the information collected to comply with the eligibility and enrollment requirements for Medicare Part C and Part D plans.

Section 4001 of the Balanced Budget Act of 1997 (BBA) (Public Law 105-33) enacted August 5, 1997, established Part C of the Medicare program, known as the Medicare + Choice program, (now

referred to as Medicare Advantage (MA)). As required by 42 CFR 422.50(a)(5), an MA-eligible individual who meets the eligibility requirements for enrollment into an MA or MAPD plan may enroll during the enrollment periods specified in §422.62, by completing an enrollment form with the MA organization or enrolling through other mechanisms that the Centers for Medicare & Medicaid Services (CMS) determines are appropriate.

Section 101 of Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Public Law 108–173) enacted December 8, 2003, established Part D of the Medicare program, known as the Voluntary Prescription Drug Benefit Program. As required by 42 CFR 423.32(a) and (b), a Part D-eligible individual who wishes to enroll in a Medicare prescription drug plan (PDP) may enroll during the enrollment periods specified in §423.38, by completing an enrollment form with the PDP, or enrolling through other mechanisms CMS determines are appropriate. *Form Number:* CMS-10718 (OMB control number: 0938-New); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 14,749,256; *Total Annual Responses:* 14,749,256; *Total Annual Hours:* 10,324,481. (For policy questions regarding this collection contact Deme Umo at (410) 786-8854.)

5. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Notice of Denial of Medicare Prescription Drug Coverage; *Use:* The purpose of this notice is to provide information to enrollees when prescription drug coverage has been denied, in whole or in part, by their Part D plans. The notice must be readable, understandable, and state the specific reasons for the denial. The notice must also remind enrollees about their rights and protections related to requests for prescription drug coverage and include an explanation of both the standard and expedited redetermination processes and the rest of the appeal process.

CMS requests approval of changes to a currently approved collection under section 1860D-4(g)(1) of the Social Security Act which requires Part D plan sponsors that deny prescription drug coverage to provide a written notice of the denial to the enrollee. The written notice must include a statement, in understandable language, of the reasons for the denial and a description of the appeals process.

Medicare beneficiaries who are enrolled in a Part D plan will be informed of adverse decisions related to their prescription drug coverage and their right to appeal these decisions. The notice provides all ways that the beneficiary can file an appeal under one section. The Part D instructions have also been revised to include a paragraph informing providers that in the case that a request for a coverage determination is denied under Part B due to step therapy requirements, a different notice should be given.

This denial notice is primarily issued to Part D plan enrollees (Medicare beneficiaries) and is most commonly sent to enrollees by mail. Relying on electronic transmission of this notice to beneficiaries is impractical. Plans are required by regulation to maintain a website by which beneficiaries can request an appeal. In this version of the notice, website information is more prominently displayed. *Form Number:* CMS-10146 (OMB control number: 0938-0976); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 525; *Total Annual Responses:* 2,887,866; *Total Annual Hours:* 721,967. (For policy questions regarding this collection contact Sara Klotz at (410) 786-1984.)

Dated: November 13, 2019.

William N. Parham, III,

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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